

**SPL Pharma Subteam
Electronic Drug Listing/Establishment Registration Lifecycle Team
Meeting Minutes – February 17, 2010**

Indexing

Randy Levin and Laurie Burke, FDA, presented SPL indexing at the last Process Team meeting and have requested Industry feedback on indexing around level of detail in terms, what parts of indications should be coded sooner, prioritization, etc.

Pharmacologic class has been indexed – available on FDA website

Action: Please contact ER/DL team leads with any feedback (and we can filter to the Leadership Team) or contact Leadership Team directly.

Establishment Registration

Questions raised around how to register multiple businesses at the same physical location addresses (eg, subsidiary and parent company). Is it possible to separate entities by slash/dash, may or may not have the same DUNS number (used to be filed as “doing business as” on paper form)? What if legal entity name change for that DUNS?

Confusion can also occur because non-US Health Authorities may be relying on DFARS website.

Conflicting feedback from D&B as to whether a DUNS can be ‘updated’ with a name change, or if a new entity would be assigned a new DUNS.

Actions: Further exploration with D&B, and Team to provide feedback on errors and successes to build best practices.

Jean Kirkeleit-Davis, Hospira to discuss acquisitions with FDA, and will provide feedback to Team.

Update on Delisting

Meeting held between Industry and FDA, including IT and DRLS representatives in December, 2009.

If companies wish to delist many legacy manufacturing NDCs or have other complicated delisting scenarios, please email FDA at edrils@fda.gov. Otherwise, continue to follow process of SPL R4 delisting process.

Current understanding is delisting is a manual process at FDA, however, delisting was supposed to be automated.

Team member has had success in delisting an NDC by submitting SPL R4 to OC with a marketing end date, and then subsequently resubmitting a 2nd time without the discontinued NDCs in metadata.

Action: Michael Fahmy will follow-up with FDA around automation progress around delisting.

Modifying/Updating NDC Code Requests

A team member has updated SPL NDC Labeler Code Request, and the update is displayed in FDA's NDC Labeler code list. However, no updated SPL COL using this Labeler Code submitted yet.

Action: Team will continue to share learnings on this point.

SPL R4 Tip:

To view a list of registered NDC labeler codes:

<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm191017.htm>